

**DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED
ACCORDING TO DIRECTIONS**

4261. Misbranding of vaginal suppositories. U. S. v. 138 Boxes * * * (and 1 other seizure action). (F. D. C. Nos. 36058, 36113. Sample Nos. 48093-L, 74278-L.)

LIBELS FILED: October 27 and November 17, 1953, Eastern District of Louisiana and Southern District of California.

ALLEGED SHIPMENT: On or about June 24, August 21, and October 5, 1953, by the Dr. J. A. McGill Co., from Chicago, Ill.

PRODUCT: 243 boxes of *vaginal suppositories* at New Orleans, La., and Los Angeles, Calif. Each box contained a copy of a leaflet entitled "Dr. J. A. McGill Co.'s Suppositories."

Examination showed that each suppository weighed approximately from 5.3 to 5.5 grams and contained approximately 47 percent ammonium alum.

LABEL, IN PART: (Box) "Contents 6 Suppositories * * * Orange Blossom Suppositories * * * Alum - Borax - Petrolatum * * * Dr. J. A. McGill Co. * * * Chicago 16, Ill."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement appearing in the labeling of the article "For Simple Irritations Of The Vaginal Tract" was false and misleading. The statement represented and suggested that the article was an adequate and effective treatment for diseases of the vaginal tract which are manifested by irritation of the vaginal tract, whereas the article was not an adequate and effective treatment for these diseases.

Further misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Directions Remove tinfoil at bedtime, insert one suppository in vagina and with your finger push it up as far as you can. Let it remain there undisturbed for three days. Then at night take a douche of warm water, and on the evening of the second day apply again as above making the application every five days excepting at monthly periods, allowing four days for the periods, then apply the suppository every five days."

DISPOSITION: December 9 and 14, 1953. Default decrees of condemnation and destruction.

VIOLATIVE SALES OF PRESCRIPTION DRUGS

4262. Misbranding of thyroid tablets, Seconal Sodium capsules, capsules containing a mixture of Seconal Sodium and Amytal Sodium, and capsules containing a mixture of extract of ergot, apiol, and oil of savin in a vehicle of castor oil. U. S. v. Center Drug Store of Durham, Inc., David G. Ridenhour, Verne D. Lea, and William A. Burwell. Pleas of guilty. Fine of \$500 and probation for 2 years against corporation and \$500 and probation for 2 years against Defendant Ridenhour; fine of \$250 against Defendant Lea and \$250 against Defendant Burwell. (F. D. C. No. 35166. Sample Nos. 59262-L, 59273-L, 59274-L, 59647-L, 59648-L, 59651-L.)

INFORMATION FILED: September 10, 1953, Middle District of North Carolina, against Center Drug Store of Durham, Inc., Durham, N. C., David G. Ridenhour, secretary-treasurer and manager of the corporation, and Verne D. Lea and William A. Burwell, pharmacists for the corporation.